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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,091	04/23/2001	Athan Kuliopulos	18475-034 (NEMC-215)	4965

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EXAMINER	
WEGERT, SANDRA L	

ART UNIT	PAPER NUMBER
1647	14

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,091	KULIOPULOS ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 6 February 2003 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, 19-21, 29 and 31, drawn to a receptor polypeptide attached to hydrophobic moieties, classified in class 530, subclass 350+.

II. Claims 18, 22-25 and 30, drawn to nucleic acids, nucleic acid constructs, host cells comprising and methods of recombinant production of a receptor polypeptide, classified in class 435, subclass 69.1+.

III. Claim 26, drawn to a method of identifying a potential therapeutic agent *in vitro*, classified in class 435, subclass 7.1+.

IV. Claim 33, drawn to a method of identifying a potential therapeutic agent *in vivo*, classified in class 435, subclass 7.1+.

V. Claims 27, 28, 32 and 34, drawn to a method of treatment by administering a polypeptide, classified in class 424, subclass 130.1+.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I and II are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The polypeptide of invention I can be used to make antibodies as well as to search for ligands, for

example. The nucleic acid of group II can be used to make a hybridization probe or can be used in gene therapy as well as in production of the protein of interest.

Furthermore Groups I and II are related as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)). In the instant case the polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Invention I is related to Invention III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide of Group I can be used therapeutically or can be used to generate antibodies, as well as to search for ligands.

Likewise, Invention I is related to Invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide of Group I can be used therapeutically or can be used to generate antibodies, as well as to search for therapeutic agents *in vivo*.

Invention I is related to Invention V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide of Group I can be used to generate antibodies, as well as in a method of treatment.

Invention II is unrelated to Inventions III-V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide of Group II is neither used in nor produced by any of the methods of Groups III-IV.

Inventions III-V are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps, measurements, personnel, and goals.

Species Elections

This application contains claims directed to the following patentably distinct species of the claimed Inventive Groups I-V. If applicant selects an Inventive Group (above), one species from the list below must be selected to be considered responsive:

i) Species of Hydrophobic moiety:

1) palmitate (C16),

2) myristoyl (C12),

3) capryl (C10),

4) caproyl (C6),

5) a phospholipid, (specify which molecule),

6) a steroid, (specify which molecule),

7) a sphingosine, (specify which molecule),

8) a ceramide, (specify which molecule),

9) octyl-glycine,

10) 2-cyclohexylalanine, or

11) benzolylphenylalanine.

The species named above are independent and distinct, each from the other, because they have different structures, different putative functions, and require completely different search terms, starting points and strategies. Furthermore the search for each hydrophobic moiety above is non-overlapping, resulting in an undue search burden.

This application contains claims directed to the following patentably distinct species of the claimed Inventive Groups I-V. If applicant selects an Inventive Group (above), *one receptor polypeptide* must be selected to be considered responsive. The applicant may specify domains from several of the GPCR's listed, provided the resultant construct or chimera comprises a **single** receptor polypeptide. It is further suggested that the applicant specify the exact composition of

the elected chimera, either by listing the receptor domains in order, or by naming an example from the Specification.

ii) Species of polypeptide receptor (select one or more):

1) GPIb/V/IX,

2) collagen receptor,

3) luteinizing hormone receptor,

4) follicle stimulating hormone receptor,

5) thyroid stimulating hormone receptor,

6) calcitonin receptor,

7) a glucagon receptor,

8) a glucagon-like peptide 1 receptor (GLP-1),

9) a metabotropic glutamate receptor,

10) a parathyroid hormone receptor,

11) a vasoactive intestinal peptide (VIP) receptor,

12) a secretin receptor,

13) a growth hormone releasing factor receptor,

14) a protease-activated receptor,

15) a cholecystokinin receptor,

16) a somatostatin receptor,

17) a melanocortin receptor,

18) an ADP receptor,

19) an adenosine receptor,

20) a thromboxane receptor,

21) a platelet activating factor receptor,

22) an adrenergic receptor,

23) a 5-HT receptor,

24) CXCR4,

25) CCR5,

26) a chemokine receptor,

27) a neuropeptide receptor,

28) an opioid receptor,

29) an erythropoietin receptor, or

30) a von Willebrand Factor receptor.

The species named above are independent and distinct, each from the other, because they have different structures, different putative functions, and require completely different search terms, starting points and strategies. Furthermore the search for each receptor is non-overlapping, resulting in an undue search burden.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of hydrophic moiety and a single disclosed species of receptor for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is found to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that are elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the grounds that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and the search required for each group is unique, and because each hydrophic moiety or receptor of Groups (i) and (ii) require a completely separate search, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Groups I through V, and must additionally elect a species of hydrophobic moiety and a species of receptor. Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

February 26, 2003

Elizabeth C. Kemmerer

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